K011643

JUN 2 8 2001

510(k) Summary Scorpio® CR Superflex™ Tibial Insert

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:

Howmedica Osteonics Corp.
59 Route 17
Allendale, NJ 07401-1677

Contact Person:

Mary-Catherine Dillon
Regulatory Affairs Specialist

Date of Summary Preparation:

June 21, 2001

Device Identification

Proprietary Name: Scorpio® CR Superflex™ Tibial Insert

Common Name: Knee Prosthesis

Classification Name and Reference: Knee Joint, Patellofemorotibial, Polymer/Metal/Polymer, Semi-Constrained, Cemented Prosthesis 21 CFR '888.3560

Predicate Device Identification

The Scorpio® CR Superflex™ Tibial Bearing Inserts are substantially equivalent to the Scorpio® CR Tibial Bearing Inserts cleared via K974556.

Device Description

The Scorpio® CR Superflex™ tibial inserts share the same critical design features as the predicate Scorpio® CR tibial inserts. They have a barb and wire locking mechanism for mating with the appropriate Howmedica Osteonics tibial trays and are compatible with the current Scorpio® patella and CR femoral components. The subject inserts will be

available in the same range of sizes and thicknesses as the current Scorpio® CR inserts.

The modifications incorporated with the Scorpio® CR Superflex™ inserts address ease of manufacturability and constraint in internal / external rotation. These modifications include increasing the anterior radius of the sagittal curve and adding a patella recess feature.

Intended Use

The intended use of the modified tibial bearing inserts is identical to that of the unmodified tibial bearing inserts. As with the predicate inserts, the modified inserts are single use devices. They are intended for mating with commercially available Howmedica Osteonics tibial trays and patellas and corresponding Howmedica Osteonics cruciate retaining femoral components. Howmedica Osteonics Scorpio® CR Total Knee components are intended for cemented fixation.

Indications

The indications for the modified Scorpio® CR Superflex™ tibial inserts will remain the same as the indications for the current Scorpio® CR inserts. These are:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure

Performance Data

Static testing has been performed to demonstrate the substantial equivalence of the subject inserts to the predicate inserts.

Statement of Technological Comparison

The fundamental scientific technology of the current Scorpio® CR tibial inserts has not changed with regard to the modified inserts. The modified inserts employ the same basic design concepts, the same materials, and the same manufacturing methods.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2001

Ms. Mary-Catherine Dillon
Regulatory Affairs Team Member
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K011643
Trade Name: Scorpio® Cruciate Retaining (CR) Superflex™ Tibial Inserts
Regulation Number: 888.3560
Regulatory Class: II
Product Code: JWH
Dated: May 25, 2001
Received: May 29, 2001

Dear Ms. Dillon:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K011643

Device Name: Scorpio® CR Superflex™ Tibial Inserts

The Scorpio® CR Superflex™ Tibial Bearing Inserts are single use devices. They are intended for mating with commercially available Howmedica Osteonics tibial trays and patellas and Scorpio® Total Knee CR femoral components, which are intended for cemented fixation.

Indications

The indications for the modified Scorpio® CR Superflex™ tibial inserts will remain the same as the indications for the current Scorpio® CR inserts. These are:

- Painful, disabling joint disease of the knee resulting from: degenerative arthritis, rheumatoid arthritis or post-traumatic arthritis
- Post-traumatic loss of knee joint configuration and function
- Moderate varus, valgus, or flexion deformity in which the ligamentous structures can be returned to adequate function and stability
- Revision of previous unsuccessful knee replacement or other procedure

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use____(Per 21 CFR 801.109)

(Optional Format 1-2-96)

D Mitchell MD for AMM

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011643